K 062471

Exhibit E 510(k) SUMMARY - Misonix Inc. AUSS-6 Ultrasonic Surgical Aspirator System and Accessories

OCT 26 2006

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

1. **Submitter's Identification**

Submitter's Name:	MISONIX INCORPORATED
Address:	1938 New Highway, Farmingdale, NY 11735
Telephone Number:	516-694-9555
Contact Person:	Ronald R. Manna
Date Prepared:	August 18, 2006

2. **Name of Device**

Proprietary Name:	Misonix Inc. FS 1000 RF Ultrasonic Surgical Aspirator System and Accessories
Common/Usual Name:	Ultrasonic Surgical System Ultrasonic Surgical Aspirator
Classification Name:	Instrument, Ultrasonic Surgical

3. **Predicate Device Information**

Misonix Inc. AUSS-6 Ultrasonic Surgical Aspirator, K050776
Misonix Inc. AUSS-5 Ultrasonic Surgical Aspirator, K012028
Radionics CUSA EXCEL Ultrasonic Surgical Aspirator System with Bone Tip, K051947

4. **Device Description:**

The FS 1000 RF Ultrasonic Surgical Aspirator System is comprised of a generator, which feeds a 23 kHz electrical signal to a piezoelectric crystals mounted in a hand-held handpiece; the crystals then vibrate at the same frequency. The titanium tip attached to the handpiece amplifies the vibration. An irrigation unit is provided to introduce irrigation solution to the operative site. An aspirator

system removes fragmented material and waste liquids from the area. Accessories include various probe tips, wrenches, tube sets and cleaning brushes.

5. **Intended Use:** The Misonix Inc. FS 1000 RF Ultrasonic Aspirator System is indicated for use in the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone) tissue in the following surgical specialties:

Neurosurgery
Gastrointestinal and Affiliated Organ Surgery
Urological Surgery
Plastic and Reconstructive Surgery
General Surgery
Orthopedic Surgery
Gynecological Surgery
Thoracic Surgery
Laparoscopic Surgery
Thoracoscopic Surgery

The system may also be combined with electrosurgery using optional RF Surgery interface components.

6. **Comparison to Predicate Device** The FS 1000 RF System and Accessories are similar in design, material and operating parameters to the Misonix Inc. AUSS-5 Ultrasonic Surgical Aspirator, the CUSA EXCEL Ultrasonic Surgical Aspirator and the Misonix AUSS-6 Ultrasonic Surgical Aspirator Systems.

Safety and Performance Data

The Misonix Inc. FS-1000 RF Ultrasonic Surgical Aspirator System and Accessories have been designed and tested to pass the following Voluntary Standards:

UL 2601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-2-2 Medical Electrical Equipment, Part 2: Particular Requirements for Safety of High Frequency Surgical Equipment
EN 60601-1-2:2001 Electromagnetic Compatibility
FCC Part 18 EMC Requirement

7. **Software Validation:** The software included with this device is not affected by the change of indication for use. All software validations were reviewed and cleared under 510(k) K032690.

8. **Sterilization Validations:** Validation statements are contained in Exhibit J.

9. **Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Output Frequency Measurements
Output Power Measurements (No Load to Maximum Load)
Tip Displacement Measurements
Irrigation Flowrate Measurements (Ultrasound On and Flush Mode)
Life Tests
Acoustic Output Test
Vacuum Flowrate and Pressure Measurements
Input Power Measurements
EMI Tests
Dielectric Tests on Mains Circuits
Patient Current Leakage and Patient Sink Current Measurements
Power Line Ground Leakage Measurements
Dielectric Tests on Patient Circuits
RF Cautery Life Tests
Dielectric Tests with RF Cautery Unit Attached
RF Cautery Unit Output Power Tests

9. **Discussions of Clinical Tests Performed:** Since the FDA has cleared the use of ultrasonic energy to ablate hard tissue in numerous 510(k) grants, no clinical tests were conducted in anticipation of this submission.

10. **Conclusions**: Based upon a review of the published literature Misonix Inc. can state that the use of an Ultrasonic Surgical Aspirator for Wound Debridement is safe and efficacious. We can also state that the AUSS-6 is substantially equivalent in this regard to the CUSA NS-100, the Misonix Inc. AUSS-5 in soft and hard tissue ablation. The AUSS-6 is also substantially equivalent to sharps debridment of wounds caused by various mechanisms such as burns, radiation and diabetes. Based upon the clinical experiences outlined herein, the Misonix Inc. AUSS-6 Ultrasonic Surgical System and Accessories pose no new issues of safety or efficacy when used for wound debridement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2006

Misonix, Inc.
% Mr. Ronald R Manna
Vice President Regulatory Affairs
1938 New Highway
Farmingdale, NY 11735

Re: K062471
Trade/Device Name: Misonix Inc. FS 1000 RF Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL
Dated: August 18, 2006
Received: August 24, 2006

Trade/Device Name: Misonix Inc. FS 1000 RF Ultrasonic Surgical Aspirator System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 18, 2006
Received: August 24, 2006

Dear Mr. Manna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

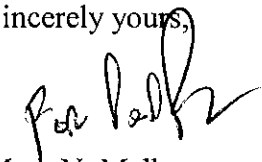
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit C

Indications for Use

K062471

Device Name: Misonix Inc. FS 1000 RF Ultrasonic Surgical Aspirator System

Indications for Use: The Misonix Inc. FS 1000 RF Ultrasonic Aspirator System is indicated for use in the fragmentation, emulsification and aspiration of both soft and hard (i.e. bone) tissue in the following surgical specialties:

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Laparoscopic Surgery
Thoracoscopic Surgery

The system may also be combined with electrosurgery using optional RF Surgery interface components.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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510(k) Number K062471